

SEP 02 2005

510(k) SUMMARY

K051671

Radiancy (Israel) Ltd.'s Radiancy SkinStation® Photoepilation System with Modified Light Unit Assembly for Hair Removal

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Manufacturer: Radiancy (Israel) Ltd.
9 Gan Rave Street
Industrial Park
Yavne
Israel
Telephone: +972-8-9438010
Facsimile: +972-8-9438020

Contact Person: Jonathan S. Kahan, Esq.
Regulatory Counsel
Hogan & Hartson L.L.P.
555 Thirteenth Street, N.W.
Washington, D.C. 20004-1109
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Date Prepared: June 22, 2005

Name of Device and Name/Address of Sponsor

Trade/Proprietary Name: Radiancy SkinStation with Modified LUA
Common Name: Pulsed Light System and Light Unit Assembly
Classification Name: Laser surgical instrument for use in general and plastic surgery
and in dermatology (21 C.F.R. § 878.4810)

Manufacturing Facility: Radiancy (Israel) Ltd.
9 Gan Rave Street
Industrial Park
Yavne, Israel

Establishment
Registration Number: 9616256
Owner/operator number: 9040071

Predicate Devices

Radiancy SkinStation Photoepilation Systems

AesThera Corporation, Model AIP

Medical Bio Care Sweden AB., ProLite

Palomar Medical Technologies, Inc., StarLux

Intended Use / Indications for Use

The SkinStation is intended to provide phototherapeutic light to the body and is generally indicated to treat dermatological conditions. The SkinStation is specifically indicated for removal of unwanted body and/or facial hair in adults with Fitzpatrick skin types I-VI.

Technological Characteristics

The Skin Station that is the subject of this 510(k) notice is the exact same device as the cleared Skin Station except for the addition of a light unit assembly specifically for hair removal in Fitzpatrick Skin Types V and VI.

Substantial Equivalence

The Radiancy SkinStation, as modified, has the same intended use and very similar indications for use, principles of operation and technological characteristics as the cleared Radiancy SkinStation, and with the AesThera Corporation Model AIP, Medical Bio Care Sweden AB. ProLite, and the Palomar Medical Technologies, Inc., StarLux. The minor difference between the Radiancy SkinStation and the predicates do not raise new issues of safety and effectiveness. Clinical data demonstrates that the Radiancy SkinStation removes unwanted body and/or facial hair in adults with Fitzpatrick skin types V-VI with only minor side effects. Thus, the Radiancy SkinStation are substantially equivalent.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Radiancy (Israel) Ltd.
c/o Mr. Jonathan S. Kahan, Esq.
Regulatory Counsel
Hogan & Hartson L.L.P.
555 Thirteenth Street
Washington, D.C. 20004-1109

Re: K051671

Trade/Device Name: Radiancy Skin Station with Modified Light Unit Assembly

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general and plastic surgery
and in dermatology

Regulatory Class: II

Product Code: GEX

Dated: June 22, 2005

Received: June 22, 2005

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2- Mr. Jonathan S. Kahan, Esq.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K051671

Device Name: Radiancy SkinStation with Modified Light Unit Assembly

Indications for Use:

The SkinStation is intended to provide phototherapeutic light to the body and is generally indicated to treat dermatological conditions. The SkinStation is specifically indicated for removal of unwanted body and/or facial hair in adults with Fitzpatrick skin types I-VI.

Prescription Use X

OR

Over-The-Counter Use _____

(Per 21 C.F.R. 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Charlene Freedman ^{for NXM}
(Division Sign-Off)
**Division of General, Restorative,
and Neurological Devices**